

**REMARKS**

Claims 1-44 are pending. Claims 1, 8, 15, and 20 are amended. Applicants disagree with all rejections and makes these claim changes only to expedite prosecution and move to allowance as soon as possible. No new matter has been added by the amendments, support therefore being found throughout the specification as filed. Favorable reconsideration in light of the remarks which follow is respectfully requested.

1. 35 U.S.C. §102 Rejections

Claim 1 is rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,876,373 to Giba et al. (hereinafter "Giba"). Applicants respectfully traverse.

Applicants recite, in independent claim 1, a catheter comprising (a) an elongate body, (b) a distal section coupled to the body, the distal section being operatively connected to a pull wire, wherein the distal section is deflectable upon application of an external force by a user via the pull wire, (c) a longitudinally extending inner lumen defined by the body and the tip, the lumen being adapted to deliver a diagnostic, prophylactic, or therapeutic agent into a subject, and (d) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section.

Giba at least does not teach or suggest a catheter comprising both (b) a distal section coupled to the body, the distal section being operatively connected to a pull wire, wherein the distal section is deflectable upon application of an external force by a user via the pull wire, and (d) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section.

Thus, Giba clearly does not teach a catheter comprising each and every element of Applicants' claim 1 and, as such, does not anticipate Applicants' claim 1. Reconsideration and withdrawal of the rejection is respectfully requested.

## 2. 35 U.S.C. §103 Rejections

Claims 2-44 are rejected under 35 U.S.C. §103(a) over Giba in view of U.S. Patent No. 5,381,782 to Delarama et al. (hereinafter “Delarama”) or U.S. Patent No. 5,454,787 to Lundquist (hereinafter “Lundquist”), and further in view of U.S. Patent No. 5,833,632 to Jacobsen et al. (hereinafter “Jacobsen”). Applicants respectfully traverse.

With respect to claim 1, as set out above, Giba at least does not teach or suggest a catheter comprising both (b) a distal section coupled to the body, the distal section being operatively connected to a pull wire, wherein the distal section is deflectable upon application of an external force by a user via the pull wire, and (d) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section.

It is further submitted that Delarama, Lundquist, and Jacobsen do not remedy these deficiencies in Giba.

Giba describes a catheter wherein a pull cable 122 is provided in connection with the distal tip 118 such that the pull cable 122 causes selective deformation of the end portion 106 (see, e.g. col. 9, lines 24-34). Similarly, Lundquist describes catheter wherein a pull wire 33 is provided in connection with the distal extremity 13 of the catheter such that pulling on the pull wire 33 causes bending of the distal extremity 13 (see, e.g. col. 3, lines 48-52). Delarama also similarly describes a catheter wherein a pair of activation wires 58 are provided in connection with the tip member 44 such that application of tensile force on the activation wires causes the tip member 44 to bend (see, e.g. col. 5, line 30 - col. 6, line 7). Thus, each of these references describe pull cables in connection with a distal end of a catheter such that the distal end bends as a result of application of force on the pull cables. Jacobsen describes a catheter guide wire 320 which has a mandrel 333 insertable therein such that insertion of the mandrel 333 causes bending and straightening of the distal end 340. In particular, Jacobsen describes two alternatives: (1) a catheter guide wire being formed with a pre-curved distal end 340 and a straight mandrel 333, wherein insertion of

mandrel 333 in the catheter guide wire 340 causes the distal end 340 to straighten and removal of the catheter guide wire 340 causes the distal end to assume its pre-curved shape, or (2) a straight catheter guide wire 340 and a mandrel 333 formed with a selected pre-curved shape, wherein insertion of pre-curved mandrel 333 causes the distal end 340 to take on the same pre-curved shape and removal of the pre-curved mandrel 333 causes the distal end 340 to straighten (see, e.g. col. 2, line 56 – col. 3, line 2). Thus, Jacobsen describes an alternative form of a distal end bending mechanism (i.e. alternative to the pull cables as described in Giza, Lundquist, and Delarama).

Clearly, none of the cited references teach or suggest a Applicants' catheter which is provided with both (1) a pull cable (or any other mechanism) for bending the distal end of a catheter as desired, and (2) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section such that the bend provided in the distal portion of a catheter can further be modified and fine-tuned so as to adjust the curvature. Further, there is absolutely no teaching or suggestion to combine and modify the references so as to provide Applicants' disclosed invention. As set out above, each of the references describes a pull cable or mandrel designed to do the same thing - bend the distal end of a catheter. None of the references teach or suggest providing, in addition to a distal end bending mechanism (pull cable or mandrel), a further and separate element which is a curvature-adjustment mechanism. Rather, this teaching comes purely from Applicants' disclosure.

Thus, claim 1 is patentable over Giba, Lundquist, Delarama, and Jacobsen. Claims 2-14 and 22-44 depend from claim 1 and, thus, also are patentable over Giba, Lundquist, Delarama, and Jacobsen. reconsideration and withdrawal of the rejections is respectfully requested.

Further, Applicants claim, in independent claim 15, a catheter comprising (a) an elongate body, (b) a distal section coupled to the body, (c) a deflection controlling

mechanism operatively connected to the distal end such that the distal section is deflectable upon application of an external force by a user on the deflection controlling mechanism, the distal section comprising an elongate flexible outer tube and an elongate slotted tube having a plurality of slots spaced longitudinally along one side of said slotted tube, with said slotted tube extending longitudinally through a major portion of said outer tube, (d) a longitudinally extending inner lumen defined by the body and distal section adapted to deliver a diagnostic, prophylactic, or therapeutic agent into a subject, and (e) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section comprising an elongate stiffener tube which is slidable longitudinally relative to the body, the curvature-adjustment mechanism providing a fulcrum spaced a distance from the distal end of the distal section, with said distance being variable by longitudinal movement of the stiffener tube to vary the radius of curvature of the distal section.

Thus, claim 15 is similar to claim 1. Similar to that set out above in connection with claim 1, Giba, Lundquist, Delarama, and Jacobsen at least do not teach or suggest both (1) deflection controlling mechanism operatively connected to the distal end such that the distal section is deflectable upon application of an external force by a user on the deflection controlling mechanism, and (2) a curvature-adjustment mechanism configured to adjust the radius of curvature of the distal section, the mechanism comprising an elongate stiffener tube which is slidable longitudinally relative to the body.

In view thereof, claim 15 is patentable over Giba, Lundquist, Delarama, and Jacobsen. Claims 16-21 and 22-44 depend from claim 15 and, thus, also are patentable over Giba, Lundquist, Delarama, and Jacobsen. reconsideration and withdrawal of the rejections is respectfully requested.

**CONCLUSION**

Reconsideration and allowance of the claims is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application. If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105** under order number 84825(47992).

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